K023931 1/2 JAN 2 8 2003

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

TriLumina Therapeutic Laser System

I. Applicant:

USALaser Therapeutics Inc.
10115 Merrimac Road
Richmond, VA 23235
1 804 320-4616

Contact Person: M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
713 / 777-5477 telephone
713 / 734-5671 facsimile
Tabs1@netropolis.net e-mail

Date Prepared: November 25, 2002

II. Device Name

Proprietary Name:	TriLumina Therapeutic Laser System
Common / Usual Name:	Low Energy Therapeutic Laser
Classification Name:	Infrared Lamp (21 CFR 890.555)
Product Code:	NHN

III. Predicate Device

The TriLumina Therapeutic Laser System is substantially equivalent to other low level therapeutic lasers currently in commercial distribution. These predicate devices include the MicroLight Corporation of America, Inc. MicroLight 830 Laser System (K010175), Acculaser, Inc. Acculaser Pro Low Level Laser System (K020657) and the MedX LCS System (K021985). These devices were cleared for introduction into interstate commerce via the FDA's 510(k) Notification process. The TriLumina Therapeutic Laser has the same intended use as and similar technological characteristics to the predicate devices.

K023935 2/2

IV. Intended Use of the Device

The TriLumina Therapeutic Laser System is a non-heating infrared lamp and is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

V. Description of the Device

The TriLumina Therapeutic Laser is an innovative, safe, easy to use, hand-held, battery operated, non-invasive, athermal low energy infrared laser device. The TriLumina Therapeutic Laser contains three gallium-aluminum-arsenide continuous wave diodes operating in the near infrared at a wavelength of 830 nanometers and a visible red light emitting diode is used as a guide beam. The device has a power output of 30 milliwatts for each GaAlAs diode with a non-collimating beam of dimensions of approximately 1 by 3 millimeters at the lens.

The Laser has an "On / Off" switch to control the power to the device and two pressure switches that when pressed energize the laser diodes. A timer automatically times the 30 second activation cycle and the delivery of 3 Joules of energy.

VI. Summary of the technical characteristics of the TriLumina Therapeutic Laser System to the referenced predicate devices.

The TriLumina Therapeutic Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared diodes to emit infrared photonic energy to the tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2003

USA Laser Therapeutics, Inc.
c/o M. Joyce Heinrich
Texas Applied Biomedical Service, Inc.
12101 –A Cullen Boulevard
Houston, Texas 77047-1601

Re: K023935
Trade/Device Name: TriLumina Therapeutic Laser System
Regulation Number: 890.5500
Regulation Name: Lamp, non-heating for adjunctive use in pain therapy
Regulatory Class: Class II
Product Code: NHN
Dated: November 25, 2002
Received: November 26, 2002

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): Pending K023935

Device Name:

TriLumina Therapeutic Laser System

Indications for Use:

The TriLumina Therapeutic Laser System is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X **OR** **Over the Counter Use:**
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

(Division Sign-Off)

510(k) Number _____

Miriam C. Provost
Division Sign-Off
Division of General, Restorative
and Neurological Devices